

REMARKS

This paper is filed in response to the office action dated March 17, 2008 and the Advisory Action dated July 10, 2008. Prior to the March 17, 2008 office action, claims 1-20 were pending. The Examiner objected to certain claim language under 35 U.S.C. §112. The Examiner rejected claims 1-4 under 35 U.S.C. §103(a) over Brimhall (United States Patent No. 5,676,656) in view of Brimhall (United States Patent No. 5,385,554). Claims 5-7 were rejected under 35 U.S.C. §103(a) in view of Brimhall '656 and Brimhall '554, and further in view of Schaffer (United States Patent No. 5,429,616). Claims 8-20 were rejected under 35 U.S.C. §103(a) over Schaffer '616 in view of Brimhall '554.

Interview with Examiner Quynh-Nhu H. Vu

Applicant expresses appreciation to Examiner Quynh-Nhu H. Vu for conducting a telephonic interview with Applicant's attorney Craig Metcalf on September 5, 2008. At that time the invention disclosed in the present application was discussed as were the pending claims. The Brimhall '656 and Brimhall '554 references were discussed. The differences between the Brimhall references and the present invention were discussed. Certain claim modifications were suggested by the Examiner and discussed in the interview. Those modifications have now been made in the claims as set forth above. It was indicated by the Examiner that claims of the scope presented above would distinguish the invention from the cited references.

Rejections Under §112

The Examiner has indicated that claims 1, 8, 13 are rejected under 35 U.S.C. §112 because of use of the phrase "such as." However, Applicant is unable to locate that phrase in the claims. The phrase "such that" is used to further define the invention. That phrase is fully definite. Clarification from the Examiner is requested.

Rejections Under 35 U.S.C. §103(a)

The legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process. See *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); *In re Saunders*, 444 F.2d 599, 170 USPQ 213 (CCPA 1971); *In re Tiffin*, 443 F.2d 394, 170 USPQ 88 (CCPA 1971), amended, 448 F.2d 791, 171 USPQ 294 (CCPA 1971); *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. If, however, the examiner does produce a *prima facie* case, the burden of coming forward with evidence or arguments shifts to the applicant who may submit additional evidence of nonobviousness, such as comparative test data showing that the claimed invention possesses improved properties not expected by the prior art. The initial evaluation of *prima facie* obviousness thus relieves both the examiner and applicant from evaluating evidence beyond the prior art and the evidence in the specification as filed until the art has been shown to render obvious the claimed invention.

A. Claims 1-4

The Examiner has rejected claims 1-4 under 35 U.S.C. §103(a) as being obvious in view of *Brimhall* '656 and *Brimhall* '554.

Claim 1 defines a "notch distance" which is the distance between the proximal end of the notch and a distal end of the opening in the distal end of the needle. This is essentially the length of the fluid channel from the needle tip to the notch. As described in the specification, blood or other body fluid flows into the needle through the needle tip and then out of the needle through the notch.

When the needle is withdrawn, including through the defined septum, it is important that blood or other bodily fluid be contained and not leak out of the septum. In order to accomplish this important result, the septum is designed to be longer than the notch distance. That is the septum is longer than the fluid path from the needle tip through the notch. In this manner there is never a point during the withdrawal of the needle where fluid is allowed to flow beyond the septum. There is not a point during the withdrawal of the needle where fluid could flow into the needle tip and then out of the notch, bypassing the septum.

Once the needle is fully withdrawn the septum is biased closed to prevent any fluid flow through the septum at that point. Thus, there is never uncontrolled fluid flow through the device. The Examiner has dismissed the importance of these features stating that "it is noted that it would have been an obvious matter of design choice to (sic) the septum having greater length than the notch distance . . ." Office Action, page 3. However, this is clearly incorrect. Without this claimed feature leakage of blood or other fluids through the device would be possible.

Furthermore, the claims have been amended to indicate that the device includes a biasing element within the housing and about the septum. The biasing element urges the septum to a closed condition. These features are not taught or suggested by either of the Brimhall references. Accordingly, the claims as amended are patentably distinct from the cited prior art.

Brimhall '656 is cited as including a septum. However, on page 4, the part that the Examiner has indicated is a septum is in fact a flash back chamber. *See*, Brimhall '656 at Col. 3, lines 10-12. The actual septum in Brimhall '656 is plug (23). Col. 2, lines 59-62.

As is apparent by reviewing Brimhall '656, particularly Fig. 2, Brimhall '656 teaches nothing about the use of a septum in conjunction with a needle having a notch. Indeed, the only teaching on the subject in Brimhall '656 is the following statement: "The proximal end of catheter hub 21 is sealed with an elastomeric plug 23, such as silicone, (see FIGS. 2 and 5) to ensure that fluid does not leak out of the proximal end of catheter hub 21." *Id.* There is

absolutely no teaching related to the length of the elastomeric hub because Brimhall '656 does not employ a notched needle. Thus, it would not have been obvious to one of ordinary skill in the art to modify the elastomeric plug 23 as set forth in claim 1, as amended.

The Examiner combines Brimhall '656 with Brimhall '554 in arguing that claims 1-4 are obvious. Brimhall '554 teaches the use of a notched needle. However, Brimhall '554 fails to teach a septum. Brimhall '554 relates to a structure for gripping a needle during needle insertion. Brimhall '554, col. 4, lines 35-48. Brimhall '554 teaches the use of two notches 18, 19 which enable the observation of blood flowing in the needle, and thus indicate that the needle has penetrated a vein.

The function of the Brimhall '554 does not require a septum. Brimhall '554 does not teach a septum of any kind, let alone a septum having the specific features presently claimed. Thus, there is no reason for one of ordinary skill in the art to combine Brimhall '554 with Brimhall '656 to result in the present invention. The two Brimhall inventions do not require the parts disclosed in the other Brimhall reference, thus the combination of the two references would not be obvious to one of ordinary skill in the art. As a result, there is absolutely no teaching in either reference which would make the presently claimed invention obvious. The Examiner's position is nothing more than prohibited hindsight reconstruction of the claimed invention by assembling unrelated parts from multiple references. Furthermore, even if the two references were combined there is no teaching of a septum having a length greater than the notch distance.

Accordingly, the Examiner is respectfully requested to withdraw the rejection of claims 1-4 under 35 U.S.C. §103(a)

Claims 5-7

In rejecting claims 5-7 the Examiner added the Schaffer reference. Schaffer is added to show the claimed feature of a biasing element. These claims are not obvious for the same

reasons that claims 1-4 are not obvious. Namely the combination of a notched needle and a septum having the claimed features is not teach, suggested, or obvious in view of any of the cited references, alone or in combination.

Claims 8-20

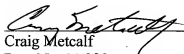
The Examiner rejected claims 8-20 under 35 U.S.C. §103(a) as being obvious over Shaffer in view of Brimhall '616. Applicant incorporates by reference the discussion of Brimhall '616.

Shaffer teaches away from the present invention and in no ways renders it obvious. Shaffer provides a pair of locking members 44, 46 which are manually squeezed together in order to compress the septum upon removal of the needle. By squeezing the locking members together, the needle hole 52 is closed in order to prevent blood or other bodily fluid from travelling up and out of the device.

This is directly contrary to the presently claimed invention which operates without the necessity of manual compression of the septum. Rather, the combination of the length of the septum and the placement of the notch assure that no blood or other fluid will exit the device. The Examiner is respectfully requested to withdraw this rejection and pass claims 8-20 to allowance.

In view of the foregoing the Applicant respectfully submits that the claims as presented are in condition for immediate allowance. If there remain any issues that could be clarified in a telephonic conference, the examiner is respectfully requested to initiate such a conference with the undersigned.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Craig Metcalf", is written over a horizontal line.

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